IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent application of:

Applicant(s):	Martin Brady et al.
Application No.:	10/753,979
Filed:	January 8, 2004
Title:	HOLLOW STYLET FOR INFUSION CATHETER SYSTEMS, DEVICES, AND METHOD
Examiner:	Laura C. Schell
Art Unit:	3767
Docket Number:	SCHWP0211USA

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The undersigned submits this brief for the Board's consideration of the appeal of the Examiner's decision, mailed December 23, 2008, finally rejecting claims 1-4, 6-8 and 11-25 of the above-identified application.

The fee for filing an appeal brief is being submitted herewith. In the event an additional fee or extension of time is necessary, the Commissioner is authorized to charge any additional fee which may be required, and further to consider this a petition for an extension of time to make the filing of this brief timely, to Deposit Account No. 18-0988 under the above-indicated docket number.

I. Real Party in Interest

The real party in interest in the present appeal is BrainLab, AG.

II. Related Appeals and Interferences

Neither appellant, appellant's legal representative, nor the prior assignee of the present application are aware of any appeals or interferences which will directly affect, which will be directly affected by, or which will have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1-4, 6-8 and 11-25 are pending in the application and stand finally rejected. Claims 5, 9 and 10 are canceled. Claims 1-4, 6-8 and 11-25 are the subject of this appeal, and a correct copy of these claims is reproduced in the Claims Appendix.

IV. Status of Amendments

No claim amendments were filed subsequent to the issuance of the final Office Action, from which this appeal is taken.

V. Summary of Claimed Subject Matter

The following is a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which refers to the specification by page and line number in brackets, and to the drawing by reference characters.

Claim 1

1. A system comprising a flexible tubular infusion catheter (140); a hollow rigid tube (110) including a proximal end (120) and a distal end and a lumen extending therebetween, wherein the hollow tube is shaped and sized to permit insertion into a lumen of the infusion catheter [5/6-21], and wherein the hollow tube is stiffer than the infusion catheter such that the hollow tube acts as a stylet for guiding the catheter through tissue to a target location in a patient's body [5/18-21]; a positioning system (310) that can be coupled to an image-guided surgical workstation (320); and a remotely detectable locator (300) on the hollow rigid tube trackable by the positioning system as the hollow rigid tube is tunneled through tissue in the patient's body toward the target location whereby the progress of the locator can be tracked and thus the position of the hollow rigid tube can be positionally tracked by the positioning system for proper positioning of the infusion catheter in relation to the patient's body into which the hollow rigid tube and catheter have been inserted and displayed on a monitor of the image-guided surgical workstation [6/28-7/3].

Claim 16

16. A system comprising a flexible tubular infusion catheter (140) including a proximal end (150) and a distal end and a lumen extending therebetween; a hollow rigid tube (110), including a proximal end (120) and a distal end and a lumen extending

therebetween, wherein the hollow tube is shaped and sized to permit insertion into the lumen of the flexible tubular infusion catheter [5/6-21], and wherein the hollow tube is stiffer than the infusion catheter such that the hollow tube acts as a stylet for guiding the catheter through tissue to a target location in a patient's body [5/18-21]; and wherein at least a portion of an inner diameter of the flexible infusion catheter snugly seals to an outer diameter of the hollow tube to prevent air from passing therebetween as the hollow tube is withdrawn from the flexible infusion catheter [5/22-28]; a positioning system (310) that can be coupled to an image-guided surgical workstation (320); and a remotely detectable locator (300) on the hollow rigid tube trackable by the positioning system as the hollow rigid tube is tunneled through tissue in the patient's body toward the target location whereby the progress of the locator can be tracked and thus the position of the hollow rigid tube can be positionally tracked by the positioning system for proper positioning of the infusion catheter in relation to the patient's body into which the hollow rigid tube and catheter have been inserted and displayed on a monitor of the image-guided surgical workstation [6/28-7/3].

Claim 18

18. A method comprising loading a hollow-tube stylet (110) with fluid; inserting the stylet into a lumen of a flexible infusion catheter (140) to provide enough stiffening to the catheter to guide the catheter through living tissue toward a target [5/18-21]; directing the stylet and the catheter through tissue to the target [6/16-22]; and withdrawing the stylet from the catheter [6/23-25], in which the withdrawing includes releasing the fluid from the stylet into the lumen of the catheter to avoid air from occupying the lumen of the catheter upon withdrawal of the stylet [6/23-30]; and wherein

the directing includes using a positioning system (310) to track the progress of a locator (300) on the rigid tube as the rigid tube is tunneled through tissue in the patient's body toward the target for proper guidance of the infusion catheter to the target [6/28-7/3].

VI. Grounds of Objection/Rejection to Be Reviewed on Appeal

A. Claims 1-4, 6, 8, 11, 12 and 16-25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,603,703 (referred to as "Elsberry") in view of U.S. Patent No. 5,342,383 (referred to as "Thomas") and further in view of Published Application No. 2006/0084943 (referred to as "Rosenman").

B. Claims 7 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Elsberry in view of Thomas and Rosenman, and in further view of U.S. Patent No. 6,743,218 (referred to as "Maginot").

C. Claims 13 and 14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Elsberry in view of Thomas and Rosenman, and in further view of U.S. Patent No. 5,137,515 (referred to as "Hogan").

VII. Argument

The rejections advanced by the Examiner are improper and should be reversed for at least the following reasons.

A. Rejection of Claims 1-4, 6, 8, 11, 12 and 16-25 under 35 U.S.C. §103(a)

Claims 1-4, 6, 8, 11, 12 and 16-25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Elsberry in view of Thomas and Rosenman. The Examiner's remarks in support of the rejection are as follows:

> Elsberry discloses a system comprising a hollow rigid tube (Fig. 1, 16; col. 3, lines 18-19), including a proximal end (above element 12, near 14) and a distal end (near 20) and a lumen extending there between, wherein the hollow tube is shaped and sized to permit insertion into a lumen of a flexible tubular infusion catheter (element 18; col. 1, lines 9-13; col. 3, lines 56-59; col. 5, lines 6-18 all disclose that while the title of the invention is directed towards aspiration, the invention can be used for infusion, and thus is also an infusion catheter), and wherein the hollow tube is stiffer than the infusion catheter (col. 4, lines 29-31 disclose that a rigid stylet is used to add rigidity to the stylet/catheter combination, which means that the stylet is inherently stiffer than the catheter, otherwise a rigid stylet wouldn't be needed) such that the hollow tube acts as a stylet for guiding the catheter through tissue to a target location.
>
> Elsberry further discloses that the lumen of the hollow tube is filled with a fluid, and in which the proximal end of the hollow tube is configured to be closed to retain the fluid within the lumen of the hollow tube (col. 4, lines 56-66). Elsberry also discloses that a fluid reservoir is coupled to the proximal end of the hollow tube (col. 3, lines 42-44). Elsberry also discloses that the hollow tube and the fluid reservoir are sized to hold enough fluid to fill the lumen of the infusion catheter after withdrawal of the hollow tube from the lumen of the infusion catheter (col. 3, lines 56-66). Elsberry further discloses a flexible tubular infusion catheter (18) including a proximal end (near 12) and a distal end (near 20) and a lumen extending there between, the lumen of the infusion catheter sized and shaped to

permit insertion of the hollow tube therein (see Fig. 1). Elsberry further discloses that the proximal end of the infusion catheter sealingly engages around the hollow tube when a portion of the hollow tube is located within the lumen of the infusion catheter (22 forms a seal around 16, alternatively see Fig. 4). Elsberry also discloses that the lumen of the catheter includes a diameter having at least two different values at different locations along the lumen of the catheter (Fig. 3 discloses that the catheter, here 26, has tow (sic, two) different diameters, a larger diameter near the holes (28) and a smaller diameter near the tip). Elsberry also discloses means for temporarily sealing the proximal end (12) of the hollow tube to retain fluid within the hollow tube.

Elsberry further discloses a method comprising loading a hollow-tube stylet with fluid (col. 8, line 64); inserting the stylet into a lumen of a flexible infusion catheter to provide enough stiffening to the catheter to guide the catheter through living tissue toward a target (col. 8, lines 51-52 and lines 65-67); directing the stylet and the catheter through tissue to the target (col. 4, lines 30-37; please note that in each claim, the phrase "as the hollow rigid tube is tunneled through tissue" is functional language, and the device disclosed by Elsberry if capable of performing the function of tunneling, especially as it is well known in the art that a catheter that first enters the vasculature must first be tunneled through the skin, fat and tunnel into the vessel in order to enter the vasculature); and withdrawing the stylet from the catheter, in which the withdrawing includes releasing the fluid from the stylet into the lumen of the catheter to avoid air form occupying the lumen of the catheter upon withdrawal of the stylet (col. 9, lines 1-2 and claim 35). Elsberry further discloses temporarily closing a proximal end of the stylet, after loading the stylet with fluid, to assist in retaining the loaded fluid within the stylet (col. 4, lines 65-67). Elsberry further discloses opening the proximal end of the stylet after inserting the stylet into the lumen of the catheter and before withdrawing the stylet, to release fluid from the stylet into the lumen of the catheter and further including infusing a fluid agent through the catheter after withdrawing the stylet (claims 31 and 35).

Elsberry, however, does not disclose that the hollow rigid tube (stylet) has a remotely detectable locator positioned on the tube allowing the stylet to be tracked by a positioning system for proper positioning of the catheter within the patient's body. Thomas, however, discloses a

stylet having a radiopaque material at the tip allowing the stylet to be tracked and viewed radiographically when positioned within the patient's body, thus allowing the physician to properly position the catheter which surrounds the stylet (abstract; col. 3, lines 10-18 in Thomas disclose that the radiopaque material is preferably barium sulfate and that this material is visualized radiographically in tracking the location of the device). The radiopaque material at the tip therefore is equivalent to the remotely detectable locator, as this is detected remotely (its position is detected and viewed on a monitor by the physician, which is obviously remote from the interior of the body in which the stylet is located). The radiographic system used by the physician and medical personnel to view the stylet is equivalent to the positioning system and image guided surgical workstation claimed, as this is a system used/viewed in surgery for positioning the stylet and catheter. Furthermore, the progress of the locator can be tracked and displayed by taking multiple radiographic images during it's (sic, its) travel through the body. While the examiner believes that it is obvious that a form of radiography used to track the device would also include displaying the resulting images on a monitor as part of an image guided workstation, such as in fluoroscopy, the Rosenman reference explicitly makes this connection obvious. Rosenman discloses a similar medical device that is tunneled through the body and includes a radiopaque marker on the device made from barium sulfate (paragraph [0042]; the same as the radiopaque marker used by Thomas), and further discloses that the device is tracked radiographically by fluoroscopy (also in paragraph [0042]. It is well known to one of ordinary skill in the art at the fluoroscopy involves imaging the patient and the device within the patient and displaying the resulting images on the monitor of a surgical guided work station). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry with the remotely detectable radiopaque locator, as taught by Thomas and further supported by Rosenman, especially since Rosenman teaches the exact same type of radiopaque marker for imaging as is used in Thomas (paragraph [0042] in Rosenman), in order to provide a guiding and positioning system to properly and accurately position the catheter and stylet for treatment.

Reversal of the rejection is respectfully requested for at least the following reasons.

Claim 1

The Examiner acknowledges that Elsberry does not disclose a hollow rigid tube having a remotely detectable locator that allows the stylet to be tracked by a positioning system. In view of this, the Examiner looks to Thomas for a disclosure of a stylet having a radiopaque material at the tip allowing the stylet to be tracked and viewed radiographically when positioned in the patient's body. The Examiner also observes that the locator and positioning system were being broadly claimed without specifics as to the nature of the positioning system. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry with a remotely detectable radiopaque locator, as taught by Thomas and further supported by Rosenman, especially since Rosenman teaches the exact same type of radiopaque marker for imaging as is used in Thomas.

The only basis provided for this asserted conclusion of obviousness is that the skilled person would have combined the teachings of the references as contended by the Examiner "in order to provide a guiding and positioning system to properly and accurately position the catheter and stylet [of Elsberry] for treatment." The Examiner, however, provides no facts supporting this stated basis.

The focus of Elsberry is on providing a hollow stylet that does not suffer from tissue being cored.

> A specific problem during catheter placement, however, is that tissue 50 can be "cored" in the distal opening if an open-ended hollow

> catheter/stylet or cannula/stylet assembly is used, and tissue can intrude through apertures in the catheter even if the assembly is not open-ended. Additionally, hollow catheter/stylet and cannula/stylet assemblies, although solid, may not have optimal rigidity, making placement within the body difficult.

Elsberry, column 1, lines 48-57. Hence, Elsberry states as his objective:

> Accordingly, the present invention provides new methods and apparatus for overcoming one or more of these deficiencies by providing a stylet defining a flow path which may be selectively opened or closed to optimize the rigidity of the stylet while minimizing tissue damage proximate an outer tubular member placed through use of the stylet.

Elsberry, column 1, lines 58-63. Consequently, the skilled person, with Elsberry in front of him, has no reasonable basis to look to Thomas or Rosenman for solutions to the problems addressed by Elsberry.

Moreover, Thomas discloses an obturator for use with an access device. Thomas, in the background section, states:

> Access to the vascular or other systems within the body of a living being are now being provided by many types of minimally invasive devices, such as needles, sheath introducers, catheters, etc. Often the procedure involved in providing access to the interior of the being's body requires the maintenance of the access device's lumen in position, e.g., within the interior of an artery, while providing a secure closure at the proximal fitting of the device, e.g., to prevent the egress of blood therefrom. In order to effect that secure closure, conventional devices, such as obturators, have been used in the access device's lumen. Such obturators typically comprise an elongated, rod-like element which when extended into the lumen of the access device <u>protrude slightly beyond its distal (open) end.</u> The obturator is held in place in the lumen via an appropriate fitting cooperating with a fitting on the access device. In order to facilitate the placement of the obturator within the access device, the obturator is typically formed of a relatively rigid material so that its tip is rigid or hard. Thus, when such a prior art obturator is used it may traumatize the tissue

which is engaged by the rigid tip, particularly if the obturator is left in place (indwells) for an extended period of time. (emphasis added)

Thomas, column 1, lines 8-32. Accordingly, the focus of Thomas is on an obturator that is intended to extend beyond the lumen into which it is inserted. With that in mind, it is not seen why the skilled person would look to Thomas since Elsberry by design (to avoid coring of tissue) provides a closed tip 26 for the catheter as shown in Fig. 3 (shown at right) of Elsberry.

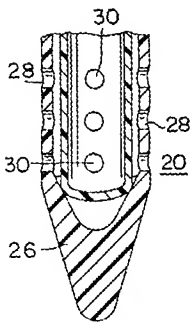


FIG. 3

Even assuming there was some reasonable basis to conclude that the skilled person would have looked to Thomas for improvements in the device of Elsberry, any resultant combination still would not yield the subject matter of claim 1. According to Thomas, "conventional obturators have included radiopaque materials therein, e.g., barium sulfate, in order to enable the user to radiographically image the device to determine its placement within the body." Radiography is the use of X-rays to view unseen or hard-to-image objects. Once the obturator has been placed, an x-ray device is used to produce a radiograph so that one can determine the placement of the obturator tip within the body. If not in the correct position, presumably the obturator would be repositioned, and then another radiograph taken using the x-ray device.

Image-guided surgery, on the other hand, is a surgical procedure where the surgeon uses indirect visualization to operate, i.e. by employing imaging instruments in real time. Existing IGS systems use different tracking techniques including mechanical, optical, ultrasonic, electromagnetic, etc.

Claim 1 recites features relating to real time, or online, tracking versus offline or static position detection according to Thomas. In particular, the claimed system

comprises, *inter alia*, a positioning system that can be coupled to an image-guided surgical workstation; and a remotely detectable locator on the hollow rigid tube trackable by the positioning system as the hollow rigid tube is tunneled through tissue in the patient's body toward the target location whereby the progress of the locator can be tracked and thus the position of the hollow rigid tube can be positionally tracked by the positioning system for proper positioning of the infusion catheter in relation to the patient's body into which the hollow rigid tube and catheter have been inserted and displayed on a monitor of the image-guided surgical workstation. That is, the position of the remotely detectable locator is tracked as the rigid tube is tunneled through the tissue in the patient's body. Neither Elsberry nor Thomas offer any suggestion of this real time tracking. Consequently, the combination advanced by the Examiner would not yield the subject matter of claim 1.

The rejection of claim 1 should be reversed.

Claim 2

Claim 2 depends from claim 1 and additionally specifies a system in which the lumen of the hollow tube is filled with a fluid, and in which the proximal end of the hollow tube is configured to be closed to retain the fluid within the lumen of the hollow tube. While the aspirating stylet of Elsberry has a valve 12 for closing the proximal end of the stylet, the proximal end of the stylet is not configured to be closed to retain fluid within the lumen of the hollow tube. This is precluded by the presence of the backfill opening 24,

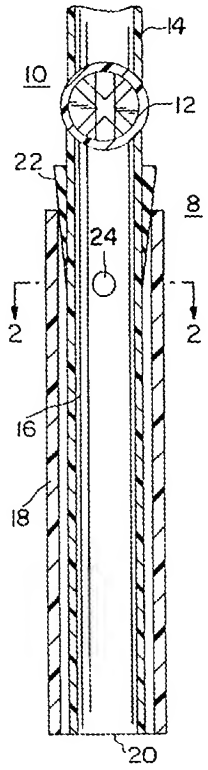


FIG. 1

which has the express purpose of allowing fluid to flow from the stylet to fill the space between the stylet and catheter.

The rejection of claim 2 should be reversed for this additional reason.

Claim 11

Claim 11 depends from claim 1 and additionally claims the image-guided surgical workstation coupled to the positioning system. For the reasons discussed above regarding real time tracking, the feature of claim 11 further distances the system from the prior art. The rejection of claim 11 should be reversed for this additional reason.

Claim 16

The above comments regarding claim 1 equally apply to claim 16. In addition, claim 16 specifies that at least a portion of an inner diameter of the flexible infusion catheter snugly seals to an outer diameter of the hollow tube to prevent air from passing therebetween as the hollow tube is withdrawn from the flexible infusion catheter. This feature is not met by reason of the backfill opening 24 which would allow air to pass between the catheter and the hollow tube as the hollow tube is withdrawn from the catheter.

The rejection of claim 16 should be reversed for this additional reason.

Claim 18

Claim 18 recites a method comprising loading a hollow-tube stylet with fluid; inserting the stylet into a lumen of a flexible infusion catheter to provide enough

stiffening to the catheter to guide the catheter through living tissue toward a target; directing the stylet and the catheter through tissue to the target; and withdrawing the stylet from the catheter, in which the withdrawing includes releasing the fluid from the stylet into the lumen of the catheter to avoid air from occupying the lumen of the catheter upon withdrawal of the stylet; and wherein the directing includes using a positioning system to track the progress of a locator on the rigid tube as the rigid tube is tunneled through tissue in the patient's body toward the target for proper guidance of the infusion catheter to the target.

The above discussion of claim 1 is generally applicable to claim 18. In particular, none of the applied references discloses using a positioning system to track the progress of a locator on a rigid tube as the rigid tube is tunneled through tissue in the patient's body toward the target. As above noted, Thomas does not disclose real time tracking of the obturator.

The rejection of claim 18 should be reversed.

B. Rejection of Claims 7 and 15 under 35 U.S.C. §103(a)

Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry in view of Thomas, further in view of Rosenman and further in view of Maginot. The Examiner contends:

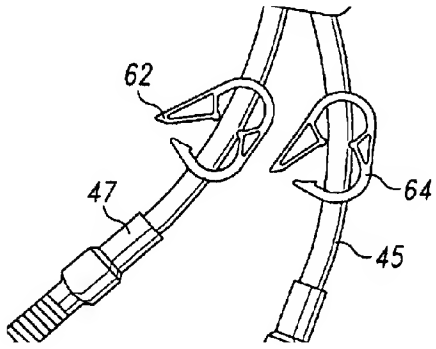
> Elsberry in view of Thomas and further in view of Rosenman discloses the device substantially as claimed except for a clamp. Maginot, however, discloses a clamp (Fig. 3, 62 and 64) to be used at the proximal end of the catheter to prevent any fluid flow through the catheter system (col. 12, lines 12-18). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry in view of Thomas and further in view of Rosenman with the clamp as taught by

Maginot in order to provide another mechanism in which stop the flow of fluid through the hollow tube.

Claim 7

First, the rejection of claim 7 should be reversed for the reasons discussed above in connection with claim 1.

In addition, the combination advanced by the Examiner does not yield the subject matter of claim 7 for the additional reason that Maginot neither discloses or suggests a catheter including a clamp for closing around a hollow tube extending through the catheter. The clamps 62 and 64 to which the Examiner refers, shown at the right, simply close the catheter upon itself.



The rejection of claim 7 should be reversed.

C. Rejection of Claims 13 and 14 under 35 U.S.C. §103(a)

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry in view of Thomas, further in view of Rosenman and further in view of Hogan (US Patent No. 5,137,515). The Examiner contends:

> Elsberry in view of Thomas and further in view of Rosenman discloses the device substantially as claimed except for a cap and a plug at the end of the proximal tube. Hogan, however, discloses a cap (Fig. 1, 34) and plug (32) for the ends of a hollow tube (col. 3, lines 3-9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry in view of Thomas and further in view of Rosenman with the cap and plug as taught by Hogan in order to provide mechanisms to seal the end of the hollow tube.

Claim 13

First, the rejection of claim 13 should be reversed for the reasons discussed above in connection with claim 1.

In addition, claim 13 calls for a cap sized and shaped to cap off a proximal end of the hollow tube. For a disclosure of a cap, the Examiner refers to Hogan.

Applicants do not claim they invented a cap for a tube. Rather, they invented a system as set forth in claim 13, which includes a cap. Hogan has nothing to do with such a system. In respect of the claimed system, Hogan does nothing more than establish that caps for tubes are known. Hogan provides no explanation as to how a cap could be used in a system like that shown in Elsberry.

For this additional reason, the rejection of claim 13 should be reversed.

Claim 14

The above comments regarding claim 13 are equally applicable to claim 14, but substituting plug for cap. The rejection of claim 14 should be reversed.

VIII. Conclusion

In view of the foregoing, it is respectfully submitted that the claims are patentable over the applied art and that the rejections advanced by the Examiner should be reversed.

Respectfully submitted,

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Claims Appendix

1. A system comprising a flexible tubular infusion catheter; a hollow rigid tube including a proximal end and a distal end and a lumen extending therebetween, wherein the hollow tube is shaped and sized to permit insertion into a lumen of the infusion catheter, and wherein the hollow tube is stiffer than the infusion catheter such that the hollow tube acts as a stylet for guiding the catheter through tissue to a target location in a patient's body; a positioning system that can be coupled to an image-guided surgical workstation; and a remotely detectable locator on the hollow rigid tube trackable by the positioning system as the hollow rigid tube is tunneled through tissue in the patient's body toward the target location whereby the progress of the locator can be tracked and thus the position of the hollow rigid tube can be positionally tracked by the positioning system for proper positioning of the infusion catheter in relation to the patient's body into which the hollow rigid tube and catheter have been inserted and displayed on a monitor of the image-guided surgical workstation.

2. The system of claim 1, in which the lumen of the hollow tube is filled with a fluid, and in which the proximal end of the hollow tube is configured to be closed to retain the fluid within the lumen of the hollow tube.

3. The system of claim 1, further including a fluid reservoir that is coupled to the proximal end of the hollow tube.

4. The system of claim 3, wherein the hollow tube and the fluid reservoir are sized to hold enough fluid to fill the lumen of the infusion catheter after withdrawal of the hollow tube from the lumen of the infusion catheter.

6. The system of claim 1, in which the proximal end of the infusion catheter sealingly engages around the hollow tube when a portion of the hollow tube is located within the lumen of the infusion catheter.

7. The system of claim 6, in which the proximal end of the tubular catheter includes a clamp that closes around the hollow tube.

8. The system of claim 6, in which the lumen of the catheter includes a diameter having at least two different values at different locations along the lumen of the catheter.

11. The system of claim 1, further including the image-guided surgical workstation coupled to the positioning system.

12. The system of claim 1, further including means for temporarily sealing the proximal end of the hollow tube to retain fluid within the hollow tube.

13. The system of claim 1, further including a cap sized and shaped to cap off a proximal end of the hollow tube.

14. The system of claim 1, further including a plug sized and shaped to plug a proximal end of the hollow tube.

15. The system of claim 1, further including a clamp sized and shaped to pinch off a portion of the hollow tube.

16. A system comprising a flexible tubular infusion catheter including a proximal end and a distal end and a lumen extending therebetween; a hollow rigid tube, including a proximal end and a distal end and a lumen extending therebetween, wherein the hollow tube is shaped and sized to permit insertion into the lumen of the flexible tubular infusion catheter, and wherein the hollow tube is stiffer than the infusion catheter such that the hollow tube acts as a stylet for guiding the catheter through tissue to a target location in a patient's body; and wherein at least a portion of an inner diameter of the flexible infusion catheter snugly seals to an outer diameter of the hollow tube to prevent air from passing therebetween as the hollow tube is withdrawn from the flexible

infusion catheter; a positioning system that can be coupled to an image-guided surgical workstation; and a remotely detectable locator on the hollow rigid tube trackable by the positioning system as the hollow rigid tube is tunneled through tissue in the patient's body toward the target location whereby the progress of the locator can be tracked and thus the position of the hollow rigid tube can be positionally tracked by the positioning system for proper positioning of the infusion catheter in relation to the patient's body into which the hollow rigid tube and catheter have been inserted and displayed on a monitor of the image-guided surgical workstation.

17. The system of claim 16, in which a proximal portion of the inner diameter of the flexible infusion catheter snugly seals to the outer diameter of the hollow tube, and in which a distal portion of the inner diameter of the flexible infusion catheter more loosely encircles the outer diameter of the hollow tube than the proximal portion.

18. A method comprising loading a hollow-tube stylet with fluid; inserting the stylet into a lumen of a flexible infusion catheter to provide enough stiffening to the catheter to guide the catheter through living tissue toward a target; directing the stylet and the catheter through tissue to the target; and withdrawing the stylet from the catheter, in which the withdrawing includes releasing the fluid from the stylet into the lumen of the catheter to avoid air from occupying the lumen of the catheter upon withdrawal of the stylet; and wherein the directing includes using a positioning system to track the progress of a locator on the rigid tube as the rigid tube is tunneled through tissue in the patient's body toward the target for proper guidance of the infusion catheter to the target.

19. The method of claim 18, further including temporarily closing a proximal end of the stylet, after the loading the stylet with fluid, to assist in retaining the loaded fluid within the stylet.

Evidence Appendix

None.

Related Proceedings Appendix

None.